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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D-0261]

Frequently Asked Questions About the New FDA Tobacco Regulations: Draft Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration is announcing the availability of a new section to the draft guidance entitled "Frequently Asked Questions About the New FDA Tobacco Regulations." The draft guidance addresses the questions most frequently asked by retailers, consumers and others about the age and photo identification requirements of the final rule restricting the sale of cigarettes and smokeless tobacco to protect children and adolescents. The new section on enforcement procedures addresses questions raised by retailers and others concerning the amount of penalties that FDA intends to seek for third and subsequent violations of the age and identification requirements.

DATES: Submit written comments on the draft guidance by April 21, 1998.
ADDRESSES: The draft guidance entitled "Frequently Asked Questions About the New FDA Tobacco Regulations," and the amendment are available on the Internet at
HTTP://www.fda.gov/, or a paper copy may be ordered free of charge by calling 1-888-FDA-4KIDS.

Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mary M. Lyda, Office of Policy (HF-11), Food and Drug Administration, 5600 Fishers Lane, rm. 14-101, Rockville, MD 20857, 301-827-3360.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 28, 1996 (61 FR 44396), FDA issued a final rule to restrict the sale and distribution of cigarettes and smokeless tobacco in order to protect children and adolescents (21CFR part 897). The final rule covers three general classes of nicotine-containing tobacco products: Cigarettes, loose cigarette tobacco, and smokeless tobacco. The final rule applies to manufacturers, distributors, retailers and importers who make, distribute, sell, and import such products.

Since February 28, 1997, the final rule has prohibited retailers from selling cigarettes, loose cigarette tobacco or smokeless tobacco to persons under the age of 18, and has required retailers to verify the age of customers under the age of 27 by checking an identification (ID) card which contains the bearer's photograph and birth date.

The draft guidance answers questions most frequently asked by retailers,

consumers, and others concerning these requirements and the agency's enforcement plans. To ensure that retailers are complying with the requirements, FDA has commissioned State officials to conduct compliance checks, during which adolescents, accompanied by State officials, attempt to purchase cigarettes or smokeless tobacco from retailers. The guidance states that for a first violation of the age and identification requirements, FDA will issue a letter notifying the retailer that it was out of compliance and informing the retailer that FDA will schedule a followup compliance check. The guidance explains that the second time a retailer is out of compliance FDA will seek civil money penalties in the amount of $250.00.

The new section that FDA is making available addresses questions concerning the amount of penalties that FDA intends to seek for third and subsequent violations of the age and photo ID provisions of the regulation. FDA intends to seek $1,500.00 for a third violation, $5,000.00 for a fourth violation, and $10,000.00 for a fifth violation. The new section provides more information concerning the civil money penalty process under which a retailer may pay the penalty or request a hearing to contest it. Because some of the answers contained in the new section represent FDA's current interpretation of new regulatory requirements, the additions constitute guidance. Therefore, FDA is publishing the new section in draft and is soliciting public comment. FDA will review received comments and, if appropriate, revise the document in response to comments.

The draft guidance does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

Interested persons may, on or before April 21, 1998, submit written comments regarding this draft guidance to the Dockets Management Branch, address above. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 12, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

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